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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-1036]

Vale Chemical Co., Inc., et al.; Withdrawal of Approval of 13 New Drug Applications and 1 Abbreviated New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration **(FDA)** is withdrawing approval of 13 new drug applications (NDA's) and 1 abbreviated new drug application (ANDA). The basis for the withdrawals is that the holders of the applications have repeatedly failed to file required annual reports for these applications.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register.)**

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301-594-2041.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs or antibiotics for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with \$314.81 (21 CFR 314.81).

In the **Federal Register** of December 2, 1998 (63 FR 66549), FDA offered an opportunity for a hearing on a proposal to withdraw approval of 13 NDA's and 1 ANDA because the firms had failed to submit the required annual reports for these applications.

Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19 101–8299, notified the agency that they no longer market the products for **NDA's** 50--088,50-129,50-189, 50-197,50-305,

and 50–3 19. W yeth-Ayerst did not request a hearing and submitted a formal request for the agency to withdraw approval of the NDA's for these products.

The holders of the other eight applications did not respond to the notice of opportunity for a hearing. Failure to file a written notice of participation and request for a hearing as required by21 CFR 314.200 constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, the Director, Center for Drug Evaluation and Research, is withdrawing approval of the applications listed in the table of this document.

Application No,	Drug	Applicant
NDA 7-112	Nisaval (pyrilamine maleate) 25 milligram (mg) Tablets	Vale Chemical Co., Inc., 1201 Liberty St., Allentown, PA 18102.
NDA 11-863	Flavihist Cough Syrup	Boyle & Co., 6330 Chalet Dr., Los Angeles, CA 90022.
NDA 50-042	Potassium Penicillin G Diagnostic Sensitivity Powder, 20,000 units	Pfizer Inc., 235 East 42d St., New York, NY 10017-5755
NDA 50-067	Compocillin-VK Chewable Wafers	Abbott Laboratories, 100 Abbott Park Rd.. Abbott Park, IL 60064.
NDA 50-088	Unipen Injection	Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101-8299.
NDA 50-121	Compocillin-VK Tablets	Abbott Laboratories.
NDA 50-122	Compocillin-V Chewable Wafers	Do.
NDA 50-129	Pen-Vee Suspension and Drops	Wyeth-Ayerst Laboratories,
NDA 50-189	Omnipen Tablets	Do.
NDA 50-197	Unipen Injection	Do.
NDA 50-305	Unipen Capsules	Do.
NDA 50-319	Omnipen Chewable Tablets	Do.
NDA 50413	Geopen Diagnostic Susceptibility Powder	Pfizer Inc.
ANDA 87-387	Aminophylline Injection USP, 25 mg/milliliter	Pharma-Serve, Inc., 216-20 98th Ave., Queens Village, NY 11429.

The Director, Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and Cosmetic Act **(21** U.S.C. **355(e)),** and under authority of **21** CFR **5.82,** finds that the holders of the applications listed in the table of this document have repeatedly failed to submit reports required by $314.81. Therefore, under this finding, approval of the applications

listed in the table of this document, and all amendments and supplements thereto, is hereby withdrawn, effective *(insert date of publication in the* **Federal Register).**

Dated: March 8, 1999

Janet Woodcock
Director, Center for Drug Evaluation and Research

[FR Dec. **99-????** Filed ??-??-99; 8:45 am]

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